



Medtronic Sofamor Danek USA, Inc.
Laveeda Leflore
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

May 18, 2018

Re: K180700

Trade/Device Name: KYPHON™ HV-R™ Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: March 15, 2018
Received: March 16, 2018

Dear Ms. Leflore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K180700

Device Name

KYPHON™ HV-R™ Bone Cement

Indications for Use (Describe)

KYPHON™ HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathological fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Medtronic Sofamor Danek USA, Inc.

May 15, 2018

Submitter	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, Tennessee 38132 Telephone: (901) 396-3133 Fax: (901) 346-9738
Contact	Laveeda Leflore Regulatory Affairs Specialist Direct Telephone: 901-399-2953 Jeff Sprague Sr. Regulatory Affairs Program Manager Direct Telephone: 901-344-1326
Date Prepared	May 15, 2018
Common Name	Kyphon™ HV-R™ Bone Cement
Regulatory Class Regulation Number Regulation Name and Device Product Classification Code	Kyphon™ HV-R™ Bone Cement Class II 21 CFR 888.3027 Polymethylmethacrylate (PMMA) bone cement NDN
Predicate Devices	1) Kyphon™ Xpede™ Bone Cement K163032, S.E. 02/27/2017 (Primary Predicate) 2) Kyphon™ HV-R™ Bone Cement K160983, S.E. 08/24/2016 The predicate devices have not been subject to a design related recall.
Description of Device	Kyphon™ HV-R™ Bone Cement is provided as a two-component system. The powder component consists of a PMMA copolymer (polymethylmethacrylate/ methyl-methacrylate-styrene copolymer) with barium sulfate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter. The powder and liquid components are mixed prior to use.

<p>Indications for Use:</p>	<p>Kyphon™ HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.</p>
<p>Comparison of Technological Characteristics with the Predicate Devices</p>	<p>The subject Kyphon™ HV-R™ Bone Cement has the same or similar indications for use, intended use, materials and fundamental scientific technology fundamental scientific technology as the predicates Kyphon™ Xpede™ Bone Cement K163032, (S.E. 02/27/2017) and Kyphon™ HV-R™ Bone Cement (K160983, S.E. 8/24/2016). The subject device utilizes equivalent implant materials, sterilization methods and bacterial endotoxin testing applying the same 20 EU/ml pyrogen limit specifications utilizing the gel clot test method as the predicate Kyphon™ HV-R™ Bone Cement (K160983, S.E. 8/24/2016).</p>
<p>Performance Data</p>	<p>Clinical literature data and non-clinical cadaveric testing is provided to support the substantial equivalence of the subject device.</p> <p>A retrospective clinical literature review was performed to examine the potential benefits and associated risks of using PMMA bone cement using a sacral vertebroplasty or sacroplasty procedure. The five articles reviewed provided clinical outcomes of 462 patients utilizing both the long-axis and short-axis surgical technique demonstrating the safety and efficacy of PMMA bone cement when used in the sacrum.</p> <p>A cadaver study in support of the expanded indication was completed. This study was performed to evaluate the extravasation behavior of the Kyphon™ HV-R™ Bone Cement during sacroplasty procedures. The study also defined the surgical procedure steps and imaging needed to minimize the risk of extravasation for the sacroplasty procedure. Both the long-axis and short-axis surgical techniques were evaluated for cement extravasation. The procedure and imaging review was performed by trained physicians. The calculated extravasation rate with the Kyphon™ HV-R™ Bone Cement was within the extravasation rate range of the published sacroplasty literature.</p>

Conclusion	Based on the provided performance data, the subject Kyphon™ HV-R™ Bone Cement is substantially equivalent to the primary predicate Kyphon™ Xpede™ Bone Cement (K163032, S.E. 02/27/2017) and Kyphon™ HV-R™ Bone Cement (K160983, S.E. 08/24/2016).
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